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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,837	03/24/2004	Wenfeng Xu	03-02	4419

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EXAMINER	
STOICA, ELLY GERALD	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
02/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/807,837	XU ET AL.	
	Examiner	Art Unit	
	ELLY-GERALD STOICA	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-22,55-60 and 74-80* is/are pending in the application.

4a) Of the above claim(s) *74-80* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-22 and 55-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

3DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/07/2007 has been entered. The Declaration under 37 CFR §1.132 of one of the inventors, WenFeng Xu, in which the inventor presents data substantiating that not all antibodies that specifically bind to IL-22RA necessarily neutralize IL-22RA activity has been considered and entered.

Status of the claims

2. As a consequence of the amendment to the claims filed on 12/07/2007, claims 1-14, 23-54 and 61-73 are cancelled. Applicant added claims 74-80. Newly submitted claims 74-80 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: in the restriction/election response submitted on 07/18/2006, Applicant elected antibodies that bind to a polypeptide consisting of the amino acid sequence of SEQ ID NO: 3 from amino acid number 1 (Pro), to amino acid number 6 (Asp). The newly elected claims do not fulfill the requirements of the election/restriction response.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 74-80 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 15-22, 55-60 and 74-80 are pending and claims 15-22 and 55-60 are currently being examined.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 15-18, 20-21 and 55-57, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Busfield (US 2002/0164689A1 in view of Hopp et al. (Hopp, TP and Woods, KR, Proc. Natl. Acad. Sci. USA: 78, 3824-28, 1981) and in further view of Lok et al. (U.S. Pat. No. 5,965,704). The claims are drawn to an antibody to a polypeptide comprising an amino acid sequence of SEQ ID NO: 3 from amino acid number 1 (Pro), to amino acid number 6 (Asp), wherein the antibody reduces or neutralizes the activity of either IL-20 (SEQ ID NO: 8) or IL-22 (SEQ ID NO: 6).

Busfield teaches an antibody that selectively binds to an isolated polypeptide consisting of a fragment of a polypeptide comprising the amino acids sequence of SEQ. ID. NO: 2 or 12, wherein the fragment comprises at least 15 contiguous amino acids of SEQ. ID. NO: 2 OR 12 (US 2002/0164689A1 **§** [0169]-(0181]). SEQ. ID. NO: 2 from Busfield is identical to SEQ. ID. NO: 2 of the instant application. (see us-10-807-837-2.rapm Result 10) and contains sequence SEQ. ID. NO: 3 from the instant application. Busfield teaches that the antibody can be of any type of the following: polyclonal, murine monoclonal, humanized antibody, human monoclonal or an antibody fragment. Also Busfield teaches that the antibody can have any of the following attached to it: a

radionuclide, enzyme, substrate, cofactor, fluorescent marker, chemiluminescent marker, peptide tag, magnetic particle, drug or toxin. Although the sequence PEDPSD is implicitly present, Busfield does not teach making an antibody specifically against the PEDPSD hexapeptide.

Hopp et al. teach that the best antigenicity is obtained by using hexapeptides (p.3826-Table 3) and especially peptides rich in P, E and D (p.3826-Table 2). The PEDPSD hexapeptide contains the highest percentage of P, E and D of any contiguous hexapeptide of the SEQ. ID. NO: 2 of the instant application.

The hexapeptide best antigenic fragment based on a antigenicity analysis and is comprised by the longer peptide fragment of Busfield et al. Busfield does not provide a detailed analysis (just that the peptide have to be located in a hydrophilic region and the fragment) but Hopp et al. actually offer scientific data to pick the best antigenic fragment which is present in the Seq. Id. No: 2 of Busfield et al.

Lok et al. (column 15, lines 14-24) teaches the use of Zcytor11 (SEQ. ID. NO: 2) polypeptides for preparing antibodies (polyclonal, murine monoclonal, or an antibody fragment) that bind to Zcytor11, which has a sequence identical to sequence SEQ. ID. NO: 2 from the application (the full 574 amino acid sequence). Also contemplated were neutralizing antibodies to Zcytor 11 (col.15, lines 57-60). Zcytor11 is an alternative name given to the IL-22 RA, which is a receptor subunit for both IL-20 and IL-22 as presented also in the instant Application.

The limitations that the antibody against the IL-22 RA reduces or neutralizes the activity of either IL 20 or IL-22 or both are inherently present as a consequence of the

structure of the antibody. While recognizing that, as presented by the inventor in the Declaration under 37 CFR §1.132 of one of the inventors, WenFeng Xu, that an antibody not all antibodies that specifically bind to IL-22RA necessarily neutralize IL-22RA activity it is considered that finding antibodies with particular features is considered routine in the art, once there are a multitude of specific antibodies obtained and available to choose from.

It would have been obvious for a person of ordinary skill in the art at the time that the invention was made to use the best antigenic features (as taught by Hopp et al.) to make antibodies as taught by Busfield and Lok and to obtain neutralizing antibodies as suggested by Lok et al. with a reasonable expectation of success. A person of ordinary skill in the art has always a good reason to pursue the known options (as articulated by Hopp et al. and prodded by Lok et al.) within her or his technical grasp. If this leads to the anticipated success, it is more likely the product not of innovation but of the ordinary skill and common sense.

7. Claims 19, 22, 58 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Busfield (US 2002/0164689A1 in view of Hopp et al. (Hopp, TP and Woods, KR, Proc. Natl. Acad. Sci. USA: 78, 3824-28, 1981) and in further view of Lok et al. (US Patent 5,965,704.) and Gonzales et al. (U. S. Pat. No. 6,133,426).

The claims are drawn to an antibody to a polypeptide comprising an amino acid sequence of SEQ ID NO: 3 from amino acid number 1 (Pro), to amino acid number 6 (Asp), wherein the antibody reduces or neutralizes the activity of either IL-20 (SEQ ID NO: 8) or IL-22 (SEQ ID NO: 6) and is further PEGylated.

The teachings of Busfield, Hopp et al. and Lok et al. were presented supra. None of them contemplate PEGylating the antibodies.

Gonzales et al. teach humanized anti-IL-8 monoclonal antibodies and variants thereof for use in diagnostic applications and in the treatment of inflammatory disorders. Also described is a conjugate formed by an antibody fragment covalently attached to a non-proteinaceous polymer (PEG).The conjugate exhibits substantially improved half-life, mean residence time, and/or clearance rate in circulation as compared to the underivatized parental antibody fragment.

In view of the utility of the antibodies claimed in the instant application, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify by PEGylation the antibodies of either of Busfield or Lok et al." in view of Hopp et al. in order to increase the serum half-life, as taught by Gonzales et al. with a reasonable expectation of success because Gonzales suggested and described the benefits of PEGylated antibodies for therapy.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 15-22 and 55-60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-22 and 55-60 of copending Application No. 11/256499. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are drawn to the same subject matter in both the instant and co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 15-22 and 55-60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-22 and 55-60 of copending Application No. 11/350375. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are drawn to the same subject matter in both the instant and co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLY-GERALD STOICA whose telephone number is (571)272-9941. The examiner can normally be reached on 8:30-17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lorraine Spector/, Ph.D.

Primary Examiner, Art Unit 1647